MR 351891

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February 7, 2013

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

2,4-Dichloro-5-(chloromethyl)pyrimidine
CAS # 7627-38-5

This letter is to inform you of the results of a LLNA study in mice with the above referenced R&D test substance. The test substance is an R&D substance and to the best of our knowledge not on the public inventory.

The test substance was evaluated for the potential to produce a dermal sensitization response in mice using the local lymph node assay (LLNA). Five groups of 5 female CBA/JHsd mice were dosed with 0% (vehicle), 5%, 25%, 50%, or 80%, of the test substance on both ears. Acetone:olive oil (4:1) (AOO) was used as the diluting vehicle. One group of 5 female mice was dosed with 25% hexylcinnamaldehyde (HCA) in AOO as a positive control. On test day 0 (first treatment day) of the assay, all mice from the 25%, 50% and 80% test concentrations were found dead approximately 2 hours after dosing. On test day 1, one mouse from the 5% test concentration was found dead and the remaining mice were sacrificed *in extremis*. Clinical signs observed from the 4 mice dosed with 5% test substance and sacrificed *in extremis* included labored breathing, swollen ears and face, splayed limbs and closed eyes. Gross observations included bright red lungs for all mice from the 5%, 25%, 50% or 80% which were found dead with the exception of one mouse from the 50% test concentration. Gross observations from mice which were sacrificed *in extremis* from the 5% test concentration included red lungs, and severe edema of the head and neck. Under the conditions of this study, the dermal sensitization potential of the test substance was unable to be determined.

Sincerely,

Company Sanitized

Substantiating Claims of Confidentiality in Submissions to the TSCA §8(e) Office

Confidential Business Information Substantiation

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.

   Yes

2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

   The claimed CBI should be maintained as confidential for [ ] or until the submitter makes the CBI public to allow sufficient time to put in place full patent protection from competitors prior to commercialization.

3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.

   The information that we are claiming as confidential has not been disclosed to any other governmental agency.

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

   Chemical identity information is maintained in restricted access databases. Access to the information is on a need-to-know basis in compliance with information security policies.

5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

   The claimed CBI has been disclosed outside the company only to those who have executed a non-disclosure agreement (NDA) covering the claimed CBI.

6. Does the information claimed as confidential appear or is it referred to in any of the following:

   Only the identity of the submitter is claimed as CBI. Submitter identity in conjunction with the test substance identity is not disclosed in any of 6a through 6d below.

a. Advertising or promotional material for the chemical substance or the resulting and product;
b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale);
c. Professional or trade publications; or
d. Any other media or publications available to the public or to your competitors.

If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

Not applicable. Only the identity of the submitter is claimed as CBI.

8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitor's access to your customers. Address each piece of information claimed CBI separately.

The claimed CBI is only the identity of the submitter. [

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9. Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?

Not applicable. Only the identity of the submitter is claimed as CBI.

10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market?

Not applicable. Only the identity of the submitter is claimed as CBI.

a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?
b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.
c. What is the substance used for and what type of product(s) does it appear in.

11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?

Not applicable. Only the identity of the submitter is claimed as CBI.

12. Do you assert that disclosure of this information you are claiming CBI would reveal:

a. confidential processes used in manufacturing the substance; Yes
b. if a mixture, the actual portions of the substance in the mixture; or No
c. information unrelated to the effects of the substance on human health or the environment? No

If your answer to any of the above questions is yes, explain how such information would be revealed.
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13. Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.

Not applicable. Only the identity of the submitter is claimed as CBI.

14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.

No